DARPA-BAA-15-06:
Electrical Prescriptions (ElectRx) BAA Frequently Asked Questions
version 2 – February 9, 2015
Additions highlighted in yellow

CONTENTS

We expect to update this FAQ document on at least a bi-weekly basis. Check the BTO Solicitations Page for updated posts.

GENERAL QUESTIONS

1. May a proposer be involved in both Technical Area 1 (TA1) and Technical Area 2 (TA2)?
Yes. Please be certain to submit complete, separate proposals for each technical area. Each proposal must focus on only one technical area.

2. May I submit (either as PI, co-I, or subcontractor) multiple TA1 and/or TA2 proposals?
Yes. However, be mindful that you are not over-allocated if multiple proposals are selected for award.

3. Do I need to submit multiple proposals if I am proposing to TA1 and TA2?
Yes. Pages 6-16 of DARPA-BAA-15-06 contain more details regarding the objectives, scope, requirements, program plan, milestones, and program metrics of TA 1 and TA 2.

4. Can I propose to a portion of a technical area?
No, each technical area is indivisible. If you feel your research interests and expertise cannot fully satisfy the objectives of a given TA, you should consider teaming with other researchers. Note that DARPA reserves the right to fund only a portion of any proposal.

5. Can proposals list co-PIs?
All proposals must list one lead PI serving as a POC for all programmatic matters. Proposals may list Co-PIs as key personnel, but the PI will have sole responsibility and authority to negotiate contract matters.

6. How will the proposals be evaluated?
A team of government reviewers will evaluate applications based on the evaluation criteria described in Section 5.1 of DARPA-BAA-15-06. The reviewers are selected based on their relevant scientific or technical expertise. Reviewers typically represent multiple government agencies, including FDA, NIH, NSF, NIST, and DoD research organizations. The review criteria are listed in the BAA and are rank ordered, with the most important criterion being listed first.

7. Should I submit via DARPA's BAA website or grants.gov?
If your organization is requesting the award of a grant or cooperative agreement, the proposal must be submitted via grants.gov. Proposals requesting procurement contracts or other transactions should be submitted via DARPA's BAA Portal (https://baa.darpa.mil).

8. I want to submit my proposal via grants.gov. However, I can't upload the MS Word version of the SOW, and the MS PowerPoint version of the summary slides. In addition, Attachment 3 to the BAA is required to be submitted as an editable MS Excel spreadsheet, but I cannot upload an MS Excel file to grants.gov. What should I do?
Please submit attachment 3, the SOW, and summary slides as PDF files on grants.gov. The BAA coordinator (DARPA-BAA-15-06@darpa.mil) will follow up with you after your proposal is submitted to request the MS Excel, Word, and PowerPoint files via email.

9. Do page limits include table of contents, list of figures, and list of tables?
No. Please see section 4.4 of DARPA-BAA-15-06 for a description of the content encompassed by the page limits.

10. Are proposers limited to only US citizens and US institutions?
No. We welcome the best ideas and research from any source. PIs, co-Is, students, post-docs, employees, subcontractors, and institutions are not required to be US citizens or based in the US. See Section 3.1.2 of the BAA for additional information.

11. What is meant by "Proposal Validity Period?"
The period of time within which a proposal submitted by an organization in response to a solicitation remains valid. For example, the costs associated with your proposed research will invariably (due to vendor quote expiration, personnel rate increases, etc.) become invalid at some point. After this period, if the contract has not been awarded, the firm is at liberty to change the financial proposal. Any attempt by the firm to change its proposal before the end of the proposal validity period is unacceptable and may result in the rejection of the proposal.

12. Section 6.2.5 of DARPA-BAA-15-60 indicates that Offerors are required to submit a small business subcontracting plan with their proposal. Although the elements of the plan are outlined in FAR 19.704, is there a corresponding DARPA form that we could utilize?
No.

13. Is a subcontracting plan needed for every subcontract that will be a part of the overall project?
No, a single subcontracting plan is required per proposal regardless of the number of subcontractors. For details, see FAR 19.702(a) (1) (found here: http://www.acquisition.gov/far/current/html/Subpart%2019_7.html) for more details regarding the description and content of the plan.

14. Is it possible to submit the application without the subcontracting plan and submit that as part of any negotiations that happen later should an award be made?
Per the BAA, "Each proposer who submits a contract proposal and includes subcontractors is required to submit a subcontracting plan in accordance with FAR 19.702(a) (1) and should do so with their proposal."

15. Can a proposal be submitted without DUNS and SAM numbers?
Per the BAA, "Unless the proposer is exempt from this requirement, as per FAR 4.1102 or 2 CFR 25.110 as applicable, all proposers must be registered in the System for Award Management (SAM) and have a valid Data Universal Numbering System (DUNS) number prior to submitting a proposal." This clause applies specifically to the organization submitting the proposal.

16. Where can I access presentations from the ElectRx proposers' day that was held in Arlington, VA on 16 December 2014?
Presentations will be uploaded to the registration website (http://www.sa-meetings.com/ElectRxProposersDay). DARPA authored presentations are already on the website. If an invited panel speaker chooses share his or her presentation, we will upload the files as we gain approval. Please check the website regularly to see if new content has been uploaded.

17. Are there any restrictions on a Large For-Profit Business requesting a Cooperative Agreement? Is there a standard contracting vehicle for large businesses?
No. Please note however, in all cases, the Government contracting officer shall have sole discretion to select award instrument type and to negotiate all instrument terms and conditions with selectees.

18. Should we include the SOW and Proposal Slides in the body of Volume 1 and also upload them separately in MS Word and MS PowerPoint formats?
Yes.

19. The BAA does not seem to list values for font size or margins associated with the text of the applications. Is there a minimum value to which we should adhere?
Per the BAA, "All pages shall be printed on 8-1/2 by 11 inch paper with type not smaller than 12 point." Margins should be no smaller than 1 inch (MS Word default).

TECHNICAL AREAS 1 & 2

20. What is meant by 'minimally invasive' and is it a requirement that all implanted devices be delivered by non-surgical means?

A long-term goal of the program is to create technologies that can be deployed without surgery or through minimally invasive surgical techniques, *i.e.,* devices and implantation procedures will be developed to reduce or ideally eliminate damage to tissue. However, the more immediate and higher priority goal of the program is to develop neuromodulation strategies that are more effective at treating diseases. This immediate goal should not be compromised by efforts to reduce invasiveness. Remember that TA1 is focused on physiology studies with the goal of identifying specific actionable targets for neuromodulation. This knowledge will serve to guide the development of minimally invasive strategies for instrumenting those targets. Work in TA2 is expected to yield novel neural interface and biosensing technologies that may reduce or eliminate tissue damage during deployment.

21. In TA1, the focus is solely on peripheral nerve stimulation and spinal cord stimulation, while brain stimulation is not applicable?

That is correct. Note: this is also true for any neural interface technologies developed under TA2. We expect that some of these technologies might also be applicable to the brain, but in this program we expect TA2 demonstrations to be focused solely on the periphery and/or spinal cord.

22. It states peripheral nervous system. However, there is mention of the spinal cord and the brain stem. Can the brain be the organ that peripheral electrical stimulation be acting on? For instance stimulating the trigeminal nerve in the face to affect brain states.

The neural interface target should be located at a peripheral nerve and/or the spinal cord (as defined in the BAA) even if the therapeutic effects are achieved in the brain or elsewhere (e.g. a visceral organ). Please see FAQ answer 21.

23. The description seems to be for peripheral treatments rather than non-invasively, or minimally invasively (under the scalp but outside of the skull) stimulating areas of the brain. When you say peripheral do you mean in a general term not putting electrodes or other stimulators into the brain?

The neural interface must target structures in the peripheral nerves and/or spinal cord, as defined by the BAA. Stimulation that directly targets the brain, even by non-invasive means, is out of scope. Please see FAQ answer 21.

24. In TA2, are electrode technologies not considered? Specifically, are electrical methods of neurostimulation not considered? What about in TA1?

We anticipate electrodes are likely necessary to support physiology studies in TA1, but in TA2 we are primarily interested in non-electrode based technologies. Previous and current investments into electrodes, microelectrode arrays, and the like are significant and will continue to provide support specifically for electrode development. Electrodes are therefore not of primary interest for technology development in ElectRx (TA2).

In TA2, we encourage proposals for innovative alternatives to electrode-based neural interface technologies. Even the most advanced microelectrode array technologies offer no ability to target specific cell types and offer limited capabilities for inhibiting neural activity. The ElectRx program seeks novel alternatives to electrodes to achieve orders of magnitude improvement of capabilities in one or

preferably more of the following areas: cell-type specific recording, stimulation, and/or inhibition; high spatial resolution to allow targeting of single fascicles (minimum) or single axons (maximum resolution); high scalability to allow high-precision, independent targeting of hundreds to thousands of locations in the nerve; chronically stable interfaces for recording or regulating neural activity at high resolution over long time scales (*i.e.* over clinically relevant durations).

25. Is this as simple as it sounds? Even if I have a new electrode design that is fundamentally different from previous electrodes there is no place for electrode research in this BAA?
Please see FAQ answer 24.

26. In TA1 animal models may be used for disease investigation, but are NHPs required for the regulatory side?
DARPA does not impose or suggest any requirements for performing animal studies to support regulatory studies. In general, NHP studies are rarely required for regulatory approval.

27. Some consider the FDA to be very conservative. How do we get all safety studies done in time?
Our goal is not to push brand new devices into clinical use in 4 years. Rather, human studies in TA1 will need to leverage existing devices. If existing devices are unable to provide the capabilities needed for your study, then it may be unfeasible to attempt those studies in humans.

28. Are non-primate models okay for TA2, but not for TA1?
Physiologically-relevant animal models of any type are acceptable in both technical areas. In TA2, proposers should choose a model that is appropriate for demonstrating the capabilities of the technology being developed.

We encourage proposers to think creatively about strategies for obtaining knowledge of human physiology to support the goals of TA1. For example, we would like to validate results of animal studies in humans wherever possible. Any disease-appropriate animal model would be acceptable in Phase 1 of TA1, but proposers must justify the selected model's appropriateness for the disease of interest. We expect final demonstrations in Phase II to be performed in a NHP or a human as appropriate and feasible.

29. For TA2, does the program require research on NHPs or humans by the end?
No, we have no preference for animal/human testing in TA2. The primary objective of TA2 is to develop and demonstrate novel technologies; it is not as essential to demonstrate in human subjects.

30. Is the program only concerned about inflammatory disease or any inflammation response?
No. Inflammatory and mental health disorders are both broad categories that include several specific diseases that are particularly burdensome for the DoD and peripheral neuromodulation strategies offer potential for creating novel treatments for those diseases. Other disease categories may be considered. In all cases, proposers must address the following. First, proposers must explain the relevance of the target disease to the DoD and/or national security. Second, proposers must provide convincing rationale for treating that disease with peripheral neuromodulation, including a description of the known or hypothesized neurophysiological circuits to be targeted to treat that disease.

31. Is TBI is out of scope? What about epilepsy?
TBI treatment is a high priority to DoD. However, TBI is too broad an indication. Proposers must identify a specific disease or symptomatology (*e.g.,* epilepsy) to be treated with neuromodulation. In all

cases, the chosen disease/injury target must be justified for its relevance to the DoD and/or national security and convincing rationale provided for treating the target disease with peripheral neuromodulation. Moreover, the benefits of treatment should be explained in quantitative terms relative to the expected impact on quality of life, return to duty/work, and other factors.

32. As a disease model, apnea has an inflammatory component. Is it in the scope of ElectRx?
Only if you can convince us of DoD relevance and impact.

33. May other diseases be studied?
Other disease categories may be considered, but in all cases, proposers must address the following. First, proposers must explain the relevance of the target disease to the DoD and/or national security. Second, proposers must provide convincing rationale for treating that disease with peripheral neuromodulation, including a description of the known or hypothesized neurophysiological circuits to be targeted to treat that disease. Bear in mind that the goal of the program is to regulate the body's response to injury, not injury treatment.

34. In TA1, is treatment of injury, such as regenerating axons, in the scope of the program?
No. The goal of program is to leverage function of neural circuit, rather than regulating any regeneration processes.

35. Do markers exist for depression that would be appropriate for feedback control?
Proposers interested in treating depression should identify known or potential biomarkers for depression.

36. Do you want TA2 proposals to address specific health problems or disease models?
A specific disease model is not required for TA2, but it is important to establish a context for your technology, particularly for the biomarker technology development. For example, for a sensor that measures molecule X, tell us why molecule X is useful for ElectRx. This use-case should then frame the context for your effort (*e.g.* specify the resolution, range, and specificity requirements that might be expected for that application).

37. In TA2, would a sensory motor system test-bed be useful for quantification of technology?
It could be an acceptable starting point to demonstrate the interface capabilities.

38. In TA2, are genetically engineered devices in scope?
Yes, they are in scope, but incremental advances to existing technologies will not be acceptable. Proposers must explain how their work in TA2 will advance beyond the state of the art.

39. What is the program's rationale for single-axon resolution requirement?
This is not an explicit requirement. Single axons represent the maximum resolution that might be needed for certain neuromodulation applications, and we would like to encourage innovative strategies for moving technology in that direction. In reality, the requirements for resolution and scale are not known and will depend on the neural circuits being targeted. TA1 studies will provide new insights into these requirements.

40. Do we need to build wireless and battery and other portions of a complete system?

No. The primary goal of TA1 is to understand the neural regulation of disease states and apply that knowledge to the design of novel neuromodulation strategies. System integration and medical product development activities are not within scope.

41. Would an application to treat depression as a coincident or downstream effect of pain be considered responsive to the call?

Generally speaking, yes, so long as the proposal highlights the relevance to DoD/national security.

42. Would an approach focused on tinnitus amelioration be considered responsive?

Generally speaking, yes, so long as the proposal highlights the relevance to DoD/national security and you provide detailed information about the proposed mechanism of action (as required in TA1 of the BAA).

43. Does proposed TA2 technology have to be portable?

Ultimately, yes. Our goal is to develop clinically viable solutions; devices that can be applied atraumatically to treat a disease state and maintain health status without further medical intervention. The scope of ElectRx, however, does not encompass complete product development and integration. If your proposed technology does not achieve portability during the course of the program, that is acceptable as long as you fully justify the scalability of your technology to meet this clinical need.

44. Page 14 of the BAA says that "…in vivo demonstrations of (at a minimum) physician-in-the-loop feedback control with limited to no off-target effects." Do teams need to include a practicing physician for non-human primate studies?

A physician collaborator is not strictly required for any aspect of ElectRx.

COST PROPOSAL

45. How important is the Cost Proposal?
The cost proposal is very important. Proposers who do not submit a well-constructed cost proposal may be considered nonresponsive to DARPA-BAA-15-06. A well-prepared cost proposal is described in section 4.4 (specifically pages 30-32) of DARPA-BAA-15-06.

46. Is the budget template (attachment 3) mandatory?
No. However, whether you choose to use this template or not, section 4.4 (specifically pages 30-32) and attachment 1 (the cost proposal checklist) of DARPA-BAA-15-06 asks you to provide the information the template asks for. Therefore, it may be easier to use the template rather than create one from scratch.

47. If I choose to use Attachment 3, will it form the entirety of my cost proposal?
No. Although the template encompasses a large portion of what section 4.4 (specifically pages 30-32) and attachment 1 (the cost proposal checklist) of DARPA-BAA-15-06 asks for, it does not include everything needed in the cost proposal. Be certain to carefully review these sections to understand what is required in the cost proposal.

48. As a subcontractor is it necessary to fill out the entire workbook or just the tabs labeled subcontractor?
Just the tabs labeled subcontractor. However, as stated in the attachment, "If a subcontractor costs more than $500K per phase, proposers must use the more detailed format for the subcontractor budget breakdown (as seen in the tabs titled Phase I,II&III)."

49. How can I access the tutorial videos for Attachment 3?
We have created the following tutorial videos to assist you in completing Attachment 3 for the ElectRx BAA:
- Part I: Example Budget: http://youtu.be/Np-OHcLnfdA
- Part II: Editing and Customizing the Blank Budget Template: http://youtu.be/Obr7H8bYIG4

You will notice that these videos were made specifically for the HAPTIX BAA (DARPA-BAA-14-30). Although the HAPTIX BAA is mentioned, the instructions are also applicable to the ElectRx BAA.

50. Please clarify the cell color legend that can be found on numerous tabs in Attachment 3.
You can edit any cell (data or formula) as necessary to fit the template to the structure of your specific project. The cell color legend is included to show you which cells contain formulas (white cells – which can be edited) and which cells are used for data entry (grey cells).

51. I am not very familiar with how to use MS Excel. What concepts are key to understand in order to use the template?
Although the template can appear very detailed and complex, it is compiled using very simple MS excel concepts. It is necessary to understand the formulas for basic arithmetic functions, how to link data within and across tabs, and absolute reference. A helpful tutorial on absolute reference can be accessed through the following link: http://youtu.be/NmVMjQzseLA.

52. Is there a recommended total cost of a proposal?
No. Convince us you have merit, be honest, and tell us how much your proposed effort is going to cost. Do not pad your budget. Be as modest as you can, but be appropriate. Bear in mind that there will be many submissions; the total amount of funding and the statement "multiple awards are anticipated" both appear in the BAA.

DARPA does not pre-determine award amounts. Proposers are required to provide a well-justified budget that is appropriate for the scope of the proposed work. Your cost should be based upon how much money is required to perform the research you feel is necessary to meet the objectives in the technical areas described in Section 1 of DARPA-BAA-15-06. Proposed costs will be scrutinized for unnecessary or inflated expenses.

If your proposal is selected to be awarded, then a government contract office will negotiate the terms of the grant or contract. During this negotiation phase, every aspect of your statement of work and cost proposal (as described in section 4.4 of DARPA-BAA-15-06) will be negotiated. Please ensure that you have followed all of the instructions in DARPA-BAA-15-06, including the required checklist in Attachment 1. This will enable the government contract office to expedite negotiations.

53. What is cost realism?
One of the review criteria is cost realism (section 5.1 of DARPA-BAA-15-06). This applies to salaries, equipment, supplies, *etc*. There is no explicit salary cap. During contract negotiations, the contract officer will examine the cost reasonableness of every item in the budget. Be sure to provide detailed quotes and justifications for your proposed expenses.

54. Do I have to provide a budget for all two phases? How can I know what my expenses will be four years from now?
Please provide complete budgets for all two phases. All phases should contain the same level of detail that is requested in section 4.4 (specifically pages 30-32) of DARPA-BAA-15-06. Put together a plan that you feel will be a likely course for the entire proposed effort. Contracts will only be awarded for Phase I with pre-negotiated options for subsequent Phase(s) included in the terms. These options will be executed (*i.e.* turned on) if DARPA is satisfied with your results and if DARPA has available funds for your effort. By negotiating these options within the scope of the DARPA-BAA-15-06, we can avoid substantial delays and problems that might arise from beginning negotiation on subsequent phases at a later date.

There may be opportunities to revise contracts at the awarding of each option. All parties will find it reasonable to update their expected costs, scope, and deliverables based on the progression of ElectRx. These re-negotiations will require the concurrence of all parties and will not be unilateral.

55. Can DARPA partially fund a proposal?
Yes. DARPA reserves the right to fully fund or partially fund a proposal. More details can be found on page 16 of DARPA-BAA-15-06.

56. What is entailed in a PI Meeting?
Section 6.2.1 of DARPA-BAA-15-06 "1. Meeting and Travel Requirements" describes PI Meetings. Briefly, PIs are expected to meet with the Program Manager and the other PIs awarded under this program. This will occur roughly once per year. It is expected that PIs will freely share their research results with each other and the Program Manager.

57. Should I budget for collaboration with parties not included in the proposed team?

Yes. If you plan to support work performed by another team (*e.g.* an informal collaboration with another group working in a different technical area), then indicate such effort as a separate task or sub-task, with associated costs itemized for those tasks and subtasks.

58. How can we budget for travel? We don't know where DARPA meetings will be located.

You should plan on sending key personnel to at least one PI meeting per year at a major US city, as well as other mission-relevant events. Be sure to justify the relevance of the non-DARPA events. A common practice is to assume that the PI meeting location will alternate between the West and East coasts (*e.g.,* California and Washington, DC). Costs can be estimated using standard lodging and per diem rates posted at www.gsa.gov/perdiem. There will be no registration fee for DARPA-sponsored meetings.

59. Should my budget be only for direct costs?

No. Please be sure to include all ODCs, indirect costs, G&A, and other indirect expenses that will be charged to the government should you be selected. This includes surgical and other patient costs that you expect will not be reimbursed by insurers.

60. Would you be able to help direct me to the office or process to get negotiated Government rates? Are they required for submission?

Pre-existing rates are not a requirement. Obtaining the pre-award accounting system approval by DCAA is the first step: http://www.dcaa.mil/preaward_accounting_system_adequacy_checklist.html. The DCAA Office should be able to provide points of contact for Defense Contract Management Agency who would be involved in the rate development process as well. However, the company will require 6 months of actuals from the approved pre-award accounting system, so it is not a quick process. Prior to conduct of the accounting system review the company can be awarded a firm fixed price contract. Under this contract type, payments are based on a milestone schedule tied to completion of work by a certain date.